Abilify Maintena® (aripiprazole) – New indication

- On July 28, 2017, Otsuka announced the FDA approval of Abilify Maintena (aripiprazole) extended-release injectable suspension, for maintenance monotherapy treatment of bipolar I disorder in adults.
    - Previously, Abilify Maintena was only approved for the treatment of schizophrenia.
- The new approval of Abilify Maintena was established in a placebo-controlled trial in adults with bipolar I disorder. The primary efficacy endpoint was time from randomization to recurrence of any mood episode.
    - Abilify Maintena demonstrated a significantly longer time to recurrence of any mood episodes vs. placebo, including both manic and mixed mood episodes.
    - However, here was no substantial difference between treatment groups in delaying time to recurrence of depressive mood episodes.
- Abilify Maintena carries a boxed warning regarding increased mortality in elderly patients with dementia-related psychosis.
- For both bipolar I disorder and schizophrenia, the recommended starting and maintenance dose of Abilify Maintena is 400 mg intramuscularly once monthly (no sooner than 26 days after the previous injection).
    - Tolerability should be established in patients who have never taken aripiprazole with oral aripiprazole prior to initiating treatment with Abilify Maintena. Due to the half-life of oral aripiprazole, it may take up to 2 weeks to fully assess tolerability.
    - After the first dose of Abilify Maintena, administer oral aripiprazole (10 mg or 20 mg) for 14 consecutive days to achieve therapeutic aripiprazole concentrations during initiation of therapy.